K062380

510(k) SUMMARY

DEC 14 2006

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Trade Name: FLOSIMPLE Arthroscopy Pump A120

Common Name: Arthroscopic Pump, Tubing Sets and Accessory

Classification Name: Arthroscope, 21 C.F.R. 888.1100

Regulatory Class: II

Product Code: HRX

Predicate Devices:

1. Arthroscopy Pump A107 (K030402)
2. Arthro-Surgimat-A103 (K000153)
3. Arthro-Surgimat-1500 (K983910)
4. Lap-Wave 3000 (K990732)

Device Description: The FLOSIMPLE Arthroscopy Pump A120 (the "A120") is a microprocessor controlled single roller pump, which functions according to the peristaltic system. The device incorporates the following major components and features: a casing, a world power supply, a rechargeable battery pack, a roller wheel, various setting keys and display elements.

The A120 performs a continuous pressure measurement to ensure that the actual pressure in the joint cavity complies with the pre-set nominal pressure. In addition, a software controlled active pressure reduction mechanism is activated if the actual pressure measured in the joint cavity exceeds the preset nominal pressure value. The device is also designed with several alarms to inform the operator in case of an overpressure. For user convenience, the device is equipped with a touch screen display. The A120 is to be mounted on a roller-wheel stand and is to be used with a specially designed cartridge tube set and with an optional remote control.

Intended Use / Indication for Use:

The FLOSIMPLE Arthroscopy Pump A120 is intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.

Substantial Equivalence:

The A120 is substantially equivalent to the Arthroscopy Pump A107 (K030402) (the "A107") manufactured by W.O.M. WORLD OF MEDICINE AG. Both the A120 and the A107 have the same intended use, function according to the peristaltic system and have a maximum flow performance of 3 l/min. The technological differences between the A120 and the A107 are minor and primarily related to the modification of the casing to allow for mounting of the A120 on a roller-wheel stand, the development of a new cartridge tube set, the offering of preselectable pressure and flow levels (knee, shoulder, small joints), the incorporation of a rechargeable power pack and of a touch screen. Unlike the A107, the A120 is a single roller pump that does not allow for the aspiration of liquids out of joint cavities. Finally, the A120 incorporates only one pressure sensor in place of the redundant pressure measurement of the A107.

Furthermore, the A120 is substantially equivalent to the Arthro-Surgimat-A103 (K000153) (the "A103"), the Arthro-Surgimat-1500 (K983910) (the "Arthro-Surgimat") and the Lap-Wave 3000 (K990732) (the "Lap-Wave"), all three manufactured by W.O.M. WORLD OF MEDICINE AG. Specifically, the A120 and the predicate devices A103 and Arthro-Surgimat have the same intended use, are designed as a single roller pump and function according to the peristaltic system. In addition, like the A103, the A120 incorporates a single ceramic sensor to perform actual pressure measurements.

Furthermore, both the A120 and the Arthro-Surgimat are designed with preselectable pressure levels (knee, shoulder, small joint) that can be programmed by the user. Finally, the A120 is substantial equivalent to the laparoscopic pump Lap-Wave with regards to the casing. Both devices are designed with a smaller casing that is to be mounted on a roller wheel stand. In sum, the technological differences between the A120 and the predicate devices are minor and raise no new questions of safety and effectiveness.

Date Prepared: August 10, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

World of Medicine AG
% Ms. Susanne Raab
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DEC 14 2006

Re: K062380
Trade/Device Name: FLOSIMPLE Arthroscopy Pump A120
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: November 29, 2006
Received: December 5, 2006

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K062380

Device Name: FLOSIMPLE Arthroscopy Pump A120

Indications for Use:

The FLOSIMPLE Arthroscopy Pump A120 is intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062380